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| APPLICATION NO.                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 08/849,525                        | 08/29/1997  | GHITA LANZENDORFER   | 435-WCG             | 3976             |
| 7590 05/19/2004                   |             |                      |                     |                  |
| NORRIS, MCLAUGHLIN & MARCUS, P.A. |             | EXAMINER             |                     |                  |
| 220 EAST 42ND STREET              |             | SHARAREH, SHAHNAM J  |                     |                  |
| 30TH FLOOR                        |             | ART UNIT             |                     |                  |
| NEW YORK, NY 10017                |             | PAPER NUMBER         |                     |                  |
|                                   |             | 1617                 |                     |                  |

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>08/849,525 | <b>Applicant(s)</b><br>LANZENDORFER ET AL. |  |
|                              | <b>Examiner</b><br>Shahnam Sharareh  | <b>Art Unit</b><br>1617                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- ~~2) ☐ This action is non-final.~~ 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 19-34 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 19-24, drawn to methods of treating immunosuppression of skin cells induced by UVB radiation.

Group II, claim(s) 25-29, drawn to methods of protecting the cells, which participate in the immune response of the skin from the damaging effects of UVB radiation.

Group III, claim(s) 30-34, drawn to compositions comprising a flavonoid.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- Group I is directed to methods of treating immunosuppression of skin cells with at least one flavonoid such as alpha-glucosylrutin. Group III is directed to various compositions that either require a hydroxycinnamic acid derivative or a cinnamic derivative or a flavonoid other than alpha-glucosylrutin. Therefore, the method embraced in Group I does not employ the compositions claimed in Group III and thus, Group I and III lack a corresponding technical feature.
- Group II directed to methods of protecting the cells, which participate in the immune response of the skin from the damaging effects of UVB with at least one flavonoid such as alpha-glucosylrutin. Group III is directed to various compositions that either require a hydroxycinnamic acid derivative or a cinnamic derivative or a flavonoid other than alpha-glucosylrutin. Therefore, the method embraced in Group I does not employ the compositions claimed in Group III and thus, Group I and III lack a corresponding technical feature.
- Group II and Group III are directed towards two different methodologies having divergent clinical effects, end points and employing different cellular process. Accordingly, they are not linked in the manner that they form a general inventive concept.

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Various dermatological compositions comprising various flavanoids with or without a cinnamic acid or hydroxycinnamic acid derivatives.

Applicant is required, in reply to this action, to elect a single species of a composition with a single species of a flavonoid and further elect whether the selected composition contains a cinnamic or hydroxycinnamic acid derivative or such element is a merely optional. Claims shall then be restricted to the elected species if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Compositions containing various flavonoids include claims 19-34  
Compositions containing various flavanoids with a cinnamic acid or a hydroxycinnamic acid include claims 23, 29-30, 34.

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The following claim(s) are generic: 19, 25, 30, 32, 34.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

- Each flavonoid containing composition is chemically and physically different than the other flavonoid containing composition. Therefore, they do not share a special technical feature.
- Those claimed compositions or methodologies that further positively employ the use of a cinnamic acid or hydroxycinnamic acid, have additional technical features that do not correspond to the effects of flavonoid alone. Additionally the claimed methods employing of a cinnamic acid or hydroxycinnamic acid provide such pharmacological benefits that no longer solely correspond to the properties of the employed flavonoids.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**RUSSELL TRAVERS**  
**PRIMARY EXAMINER**